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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,086

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EXAMINER

BERNSHTEYN, MICHAEL

ART UNIT

PAPER NUMBER

1713

MAIL DATE

DELIVERY MODE

09/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/523,086

Applicant(s)

HERFERT ET AL.

Examiner

Michael Bernshteyn

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 07/27/2007.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action follows a response filed on July 16, 2007. Claim 1 has been amended; claim 31 has been cancelled; no claims have been or added.
2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 16, 2007 has been entered.
3. In view of the amendment (s) and remarks, the rejection(s) of claim(s) 1-19 under 35 U.S.C. 102(b) and 103(a) have been withdrawn. Applicant's arguments with respect to claims 1-19 have been considered but are moot in view of the new ground(s) of rejection.
4. Claims 1-19 are pending.

Claim Rejections - 35 USC § 103

5. The text of this section of Title 35 U.S.C. not included in this action can be found in a prior Office Action.
6. Claim 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable as obvious over Sun et al. (U.S. Patent 6,124,391) in view of Le-Khac et al. (WO 96/30442), for rationale recited in paragraphs 7 and 8 of Office Action dated on September 13, 2006.

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7. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable as obvious over Sun et al. and Le-Khac as applied to claims 1-17 above, and further in view of Schulz et al. (U. S. Patent 5,869,033).

The combined teaching of Sun and Le-Khac does not disclose the particles wherein the organophilic clay contains long chain alkyl radicals having 14 to 22 carbon atoms.

Schulz discloses that the quaternary ammonium compounds used in preparing the organophilic clay component of the skin-protecting composition used in the method of the invention typically have one or two long-chain substituents, e.g., 14-20 carbon atoms, and two or three short-chain substituents such as methyl groups. A preferred quaternary ammonium compound is dimethyl dihydrogenated tallow ammonium chloride. Because the tallow contains a large proportion of stearic acid, which contains 18 carbon atoms, the resulting clay is often referred to as a quaternium 18 clay, e.g., quaternium 18 bentonite, or quaternium 18 hectorite. The composition and preparation of such organophilic clays is discussed in U.S. Pat. No. 4,861,584. Preferred organophilic clay for use is quaternium 18 bentonite.(col. 4, lines 1-15).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate organophilic clay selected from tallow derivatives as taught by Schulz in Sun and Le-Khac's superabsorbent polymers because a superabsorbent polymer containing an organophilic clay effective to inactivate irritating fecal proteolytic enzymes dispersed in a pharmaceutically acceptable non-toxic dermatological vehicle (US'033, col. 1, lines 53-57).

Thus, the combination of Sun, Le-Khac and Schulz renders the instant claims 1-19 *prima facie* obvious absent evidence of unexpected results commensurate in scope to the claims.

Response to Arguments

8. Applicants traverse the rejection of claims 1, 2, 7-10 and 16 under 35 U.S.C. 102(b) as being anticipated by Le-Khac et al. (WO 96/30442). Applicant's arguments, see remarks, filed on July 16, 2007, with respect to claims 1, 2, 7-10 and 16 have been fully considered and are persuasive. The rejection of claims 1, 2, 7-10 and 16 under 35 U.S.C. 102(b) as being anticipated by Le-Khac et al. (WO 96/30442) has been withdrawn.

9. Applicants traverse the rejection of claims 18 and 19 under 35 U.S.C. 103(a) as being unpatentable as obvious over Sun et al. and Le-Khac as applied to claims 1-5 and 7-17 above, and further in view of Beerse et al. (US 2002/0006886). Applicant's arguments, see remarks, filed on July 16, 2007, with respect to claims 18 and 19 have been fully considered and are persuasive. The rejection of claims 18 and 19 under 35 U.S.C. 103(a) as being unpatentable as obvious over Sun et al. and Le-Khac as applied to claims 1-5 and 7-17 above, and further in view of Beerse et al. (US 2002/0006886) has been withdrawn.

10. Applicants traverse the rejection of claims 1-17 under 35 U.S.C. 103(a) as being unpatentable as obvious over Sun et al. (U. S. Patent 6,124,391) and Le-Khac (WO

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96/30442). Applicant's arguments have been fully considered but they are not persuasive.

11. It appears that the focal Applicants argument resides in the contention that the *maximum* amount of inorganic powder added to the SAP particles, as disclosed in the '391 patent, is 10 wt%, in contrast the present claims specifically recite the *minimum* amount of about 15% (pages 11-12, the bridging paragraph), and that the claimed amount of about 15% to about 35% because by increasing the amount of clay to 15 wt% in accordance with presently claimed invention, fine-sized particles having a diameter less than 200 μm drops substantially to 4.5 wt %. Further increasing the amount of clay up to 35 wt% results in further decreases in the amount of fine-sized SAP particles (page 12, 2nd and 3rd paragraphs).

12. It is noted that In view of substantially identical superabsorbent particles and the method of obtaining such particles between Sun and the Applicants, it is the examiner position that in both cases the clay partly present in the vicinity of surfaces of the superabsorbent particles. As it well known, an introducing of clay in the amounts about 10% as in prior art or about 15-35% as claimed by the Applicants, will cause not only *surface-crosslinked* superabsorbent particles containing the clay *in the vicinity of the surfaces* of the superabsorbent particles as per claim 1, but also homogeneously distributing of the clay throughout superabsorbent particles. It is well known that for achieving the effect of surface-crosslinking of superabsorbent particles it is enough the amount up to 10% of a surface-crosslinked compound, more preferably less than 5% (U. S. Patents 4,541,871, 4,824,901, 4,789,861, 4,587,308, 4,734,478, 5,164,459,

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4,020,780, 5,562,646, 5,599,335; WO-92/16565, WO-90/08789, WO-93/05080, EP-509708, etc.).

Therefore, it is clear, that if the composition contains up to 35% of the clay, this clay cannot be only in the vicinity of the surfaces of the superabsorbent particles, and the most part of it would be distributed throughout superabsorbent particles.

13. Furthermore, it is not clear why the optimum range within 15-35% only based on the amount of fine-sized particles having a diameter less than 200 μm ? The maximum amount of the clay is 35% that gives the minimum amount (1.2 wt%) of fine-sized particles having a diameter less than 200 μm (the specification, Table of Example 5, page 30). According the tendency of Applicant's experiments, it make sense to increase the amount of clay up to 50%, which probably can further drop the amount of fine-sized particles having a diameter less than 200 μm .

14. In response to Applicants objective evidence demonstrating the new and unexpected results (page 12, the last paragraph), it is noted that the Applicants have to use the closest prior art (U. S. Patent 6,124,391) to run a consecutive "back-to-back" test to show unexpected results, if any. "Showing unexpected results over one of two equally close prior art references will not rebut prima facie obviousness unless the teachings of the prior art references are sufficiently similar to each other that the testing of one showing unexpected results would provide the same information as to the other". *In re Johnson*, 747 F.2d 1456, 1461, 223 USPQ 1260, 1264 (Fed. Cir. 1984).

Objective evidence which must be factually supported by an appropriate affidavit or declaration to be of probative value includes evidence of unexpected results,

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commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See, for example, *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984) ("It is well settled that unexpected results must be established by factual evidence." "[A]ppellants have not presented any experimental data showing that prior heat-shrinkable articles split. Due to the absence of tests comparing appellant's heat shrinkable articles with those of the closest prior art, we conclude that appellant's assertions of unexpected results constitute mere argument."). See also *In re Lindner*, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972); *Ex parte George*, 21 USPQ2d 1058 (Bd. Pat. App. & Inter. 1991). See MPEP 716.01(c).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bernshteyn whose telephone number is 571-272-2411. The examiner can normally be reached on M-F 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on 571-272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Bernshteyn
Patent Examiner
Art Unit 1713

MB
09/14/2007


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